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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/646,545

08/21/2003

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08/18/2009

EXAMINER

ALTER, ALYSSA MARGO

ART UNIT

PAPER NUMBER

3762

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/646,545	Applicant(s) HINE ET AL.	
	Examiner Alyssa M. Alter	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 11-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-6 and 11-13 have been considered but are not persuasive. The Applicant argues that Pohndorf et al. does not disclose "at least one electrical contact element of the one or more electrical contact elements of the first adapter that is located in a different location along the internal surface than the one or more electrical contact elements of the second adapter".

However, since Pohndorf et al. possesses multiple contacts on his adapters, as depicted in figures 6 and 7, the first two contacts are the first two claimed contacts for the first adapter AND on the second adapter, the next two contacts are the other claimed contacts on the second adapter. Therefore each adapter will have different contacts at different locations. Furthermore, since this is a "comprising claim" the adapters are not precluded from having extra contacts.

Therefore, the claims remain rejected under Pohndorf et al. as detailed below.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1, 3-4, 6, 11-13 and 16-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious Pohndorf et al. (US 4,628,934). Pohndorf et al. discloses a pacemaker with a connector bore for electrically and mechanically connecting the implantable medical device (IMD) with two adapters and multi-electrode leads as displayed in figures 6 and 7. The adapters upsize the leads prior to the insertion into the connector bore within the IMD. The array of lead connector elements are displayed in figure 2 as "sleeves 151 and 152 (in contact with rings 141 and 142) (col. 7, lines 63-64)". The sleeves are connected to electrodes, with a conductor for each electrode. The two adaptors, which the examiner considers to be a plurality of adaptors, have an inner lumen for engaging the sleeves of the lead with rings to create an electrical and mechanical connection. In addition, the adaptors have an external surface used for engagement with the electrical bore. This engagement surface has two contact zones, the pin as the first zone and sleeves of the lead as the second zone, which connects within the IMD with the socket and rings, respectively.

Since the lead connectors are located circumferentially around the lead, the examiner considers the connectors to be connector rings. In addition, a connector ring

is located adjacent to the sealing ring and distal to the remainder of the array of lead connectors. Therefore, since the ring conductor makes contact with the bore of the IMD by means of the adaptor, the connector ring is located distal to the array of lead connector elements and electrically connected to the IMD bore.

Within the adaptor-lead connector, there are two sealing rings. One sealing ring, as previously mentioned, is located distal to the array of connector elements located on the lead. The other sealing ring is located on the adaptor located proximal to the array of connector elements.

Outer surface of a male connector piece closely matched the inner surface of a female connector piece the connection assembly is dimensioned to be press fit. Therefore, since the sleeves or array of lead connector elements on the cylindrical male piece closely match the rings or contact elements located within the adaptor on a cylindrical female piece, the connection assembly is press fit.

As to claim 1, Pohndorf et al. discloses two adapters, as seen in figures 6 and 7, sized to engage in the connection bore of the IMD. Both of the adapters have internal surfaces which form lumens sized to receive a single lead. Specifically “the second adapter ...forming a second lumen to receive the single lead”. Therefore, Pohndorf et al. meets the limitation by disclosing two adapters with lumens sized or formed to receive the single lead.

Additionally, since Pohndorf et al. possesses multiple contacts on his adapters, as depicted in figures 6 and 7, the first two contacts are the first two claimed contacts for the first adapter AND on the second adapter, the next two contacts are the other

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claimed contacts on the second adapter. Therefore each adapter will have different contacts at different locations. Furthermore, since this is a “comprising claim” the adapters are not precluded from having extra contacts.

Also, Pohndorf et al. discloses in col. 6, line 31, the header 38 is made of insulative material. Since the header, which is configured to be in electrical contact with the adapter(s), is made of insulating material it is understood that the adapters, which are in electrical contact with the leads, would also inherently be made of similar material. Constructing the header and adapters from insulative material assured that the electrical contacts will not engage with the lead until the lead is properly inserted and aligned (see figure 5 and 7). Thus the examiner considers Pohndorf et al. to necessarily possess an insulative sleeve within the inner adapter lumen.

In the alternative, although the examiner considers Pohndorf et al. to disclose an insulative sleeve within the inner adapter lumen, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate an insulative inner sleeve to provide the predictable results of preventing improper electrical engagement, as well as, assuring that the electrical charge is directed to the header 38 and not dissipated by the adapter. The incorporation of an insulative sleeve would also prevent the adapter from functioning like an electrode.

Additionally, it is well known in the art to employ an insulative sleeve into an adapter lumen or header lumen in order to prevent unnecessary or unwanted electrical engagement with a lead.

2. Claim 2 is rejected under 35 U.S.C. 103(a) as being obvious over Pohndorf et al. (US 4,628,934). Pohndorf et al. discloses the claimed invention except for the external surface conforming to industry standard. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the external surfaces as taught by Pohndorf et al. with external surfaces conforming to industry standard since it was known in the art to construct medical devices to an industry standard to provide the predictable results of ensuring quality and uniformity.

3. Claim 5 is rejected under 35 U.S.C. 103(a) as being obvious over Pohndorf et al. (US 4,628,934) in view of Peers-Trevarton (US 4,469,104). Holleman et al. discloses the claimed invention except for the protrusions for each contact element within the array of lead contact elements. Peers-Trevarton teaches that it is known to utilize protrusions and depressions to securely mechanically and electrically engage the lead. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrical connections of the lead as taught by Pohndorf et al. with the electrical and mechanical connections as taught by Peers-Trevarton since such a modification would be a substitution of known functional equivalents by substituting electrical connectors which would provide the predictable results of electrically engage the lead.

Claim Objections

1. Claims 1-6, 13 and 16-22 are objected to because of the following informalities:
Clarity is required in indicating how both adapters can be connected at the same time to the same bore. Therefore the claims should be in KIT format since they are just a listing of parts. Appropriate correction is required.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
Art Unit 3762